

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**1. CERTIFICATE NUMBER:** 23-R-0012  
**CUSTOMER NUMBER:** 286

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )**

**Glaxo Smith Kline**  
709 Swedeland Road, P.O. Box 1539  
King Of Prussia, PA 19406

Telephone: (610) -270-4800

**3. REPORTING FACILITY** ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

**FACILITY LOCATIONS ( Sites ) - See Attached Listing**

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

## **ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
  - 2) Each principal investigator has considered alternatives to painful procedures.
  - 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
  - 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
**( Chief Executive Officer or Legally Responsible Institutional Official )**

b6, b7c

**DATE SIGNED**

11/21/05

NOV 23 2005

DEC 13 2005

**APHIS Form 7023 Site List**

The following sites have been reported by the facility.

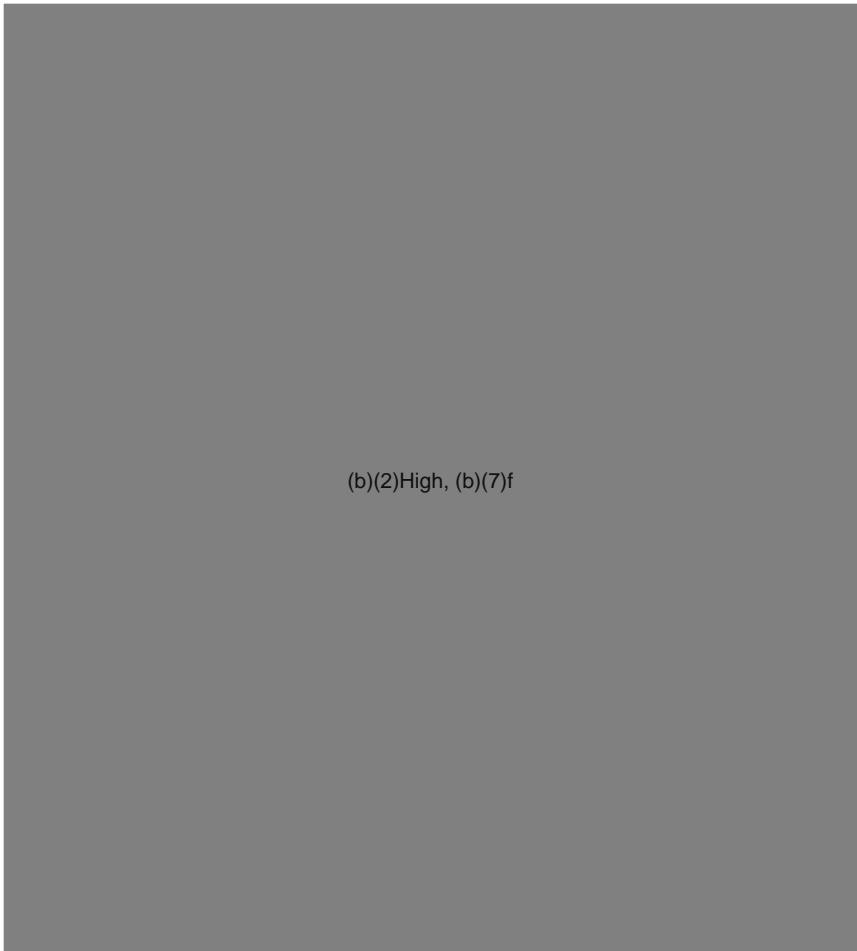
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Registration Number: 23-R-0012  
Customer Number: 286  
Facility: GlaxoSmithKline  
709 Swedeland Road  
P.O. Box 1539  
King of Prussia, PA 19406-0939  
(610)270-4800

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GlaxoSmithKline (Valley Forge Area)  
709 Swedeland Road  
King of Prussia, PA

(b)(2)High, (b)(7)f



NOV 28 2005

DEC 13 2005



GlaxoSmithKline

GlaxoSmithKline  
PO Box 13398

(b)(2)High, (b)(7)f

[www.gsk.com](http://www.gsk.com)

**TO:** *B. Walton*  
*Attending Veterinarian*

**FROM:**

b6, b7c

**SUBJECT:** *Animal Care Regulations and Standards*

**DATE:** *1 November 2005*

During the period from October 1, 2004 to September 30, 2005 there were no exceptions to the regulations or standards identified by the IACUC at our site in

(b)(2)High, (b)(7)f This includes having no exceptions to our exercise plan and all nonhuman primates participated in the environmental enrichment program.

DEC 13 2005

NOV 23 2005



GlaxoSmithKline

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19406-0939

Tel. 610 270 4800  
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**TO:**

**L. Meunier**  
*Attending Veterinarian*

**FROM:**

b6, b7c

**SUBJECT:** *Animal Care Regulations and Standards*

**DATE:** *27-October-2005*

During the period from October 1, 2004 to September 30, 2005 there were no exceptions to the regulations or standards identified by the IACUC at our sites in

(b)(2)High, (b)(7)f

This includes

having no exceptions to our exercise plan and all nonhuman primates participated in the environmental enrichment program.

DEC 13 2005

**Explanation of Animals Listed in Column E  
2004-2005 USDA Annual Report for Registration Number 23-R-0012**

**Dogs**

Two (2) dogs are listed in Column E. Both dogs were part of Safety Assessment studies that were conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Nonclinical Laboratory Studies, 21 CFR Part 58.

**Toxicity Study for development of a novel anti-cancer compound**

Two (2) dogs on this study developed vomiting, depression, and weight loss after being dosed with a novel anti-cancer compound. In each case supportive care was given. This included fluid therapy, parental nutritional supplements, alternative feeding patterns and novel foods. Administration of additional therapy such as anti-emetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

**Ferrets**

Forty nine (49) ferrets are listed in Column E.

**Studies for development of novel anti-emetic compounds for the treatment of chemotherapy induced emesis**

Forty nine/fifty four (49) ferrets were involved in studies to evaluate novel anti-emetic compounds. Animals were given novel anti-emetic compounds plus vehicle or vehicle alone then given a known agent that causes vomiting. Some animals were used as controls, but the majority of ferrets were drug-treated. All animals showed mild to moderate signs of sedation (quiet and sleeping) within the first few hours of dosing and controls did show signs of emesis (vomiting and/or retching). Signs of emesis were not seen routinely in animals treated with novel anti-emetic compounds. Animals were closely monitored. Some animals exhibited anorexia and had weight loss (10-15%) by 72 hours. All animals were euthanized by the 3<sup>rd</sup> day post-dosing. Known anti-emetic compounds or analgesics were not given because of interference with study results.